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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SALMON, KATHERINE D	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,652	GUO, YONGJUN	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *6-24 and 29-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,25-28,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/27/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1, Claims 1-5, 25-28, and 33-34 in the reply filed on 3/13/2006 is acknowledged.

2. The requirement is deemed proper and is therefore made FINAL.

3. Claims 6-24 and 29-32 are withdrawn from consideration as being drawn to a nonelected group.

4. Accordingly an action on the merits of Claims 1-5, 25-28, and 33-34 is set forth below.

Information Disclosure Statement

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

6. With regard to Figure 3, the bars for the "African American" and "Caucasian" populations are not differentiable. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 25-28, and 33-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claim 1 is drawn to an isolated nucleic acid molecule comprising the sequence of SEQ ID No. 1. Claim 2 is drawn to an isolated nucleic acid molecule comprising a sequence complementary to the sequence of SEQ ID No. 1. Claims 3-4 are drawn to a vector wherein the reporter gene sequence encodes luciferase. Claim 5 is drawn to a

host cell. Claim 25 is drawn to a kit comprising a first oligonucleotide probe which anneals specifically with a target portion of the mammal's genome, wherein said first probe comprises a first fluorescent label and a first fluorescence quencher attached to separate nucleotide residues thereof and said target portion includes the nucleotide residue located at position 69 of SEQ ID No. 1 and a pair of primers for amplifying a reference portion of the FGF-3 gene wherein said reference portion includes the nucleotide residue located at position 69 of SEQ ID No. 1. Claim 26 is drawn to a kit including DNA polymerase having 5' to 3' exonuclease activity. Claim 27 is drawn to a kit further comprising a second oligonucleotide probe, wherein said first probe is completely complementary to said target portion if the nucleotide residue located at position 69 of SEQ ID No. 1 is cytosine and said second oligonucleotide probe is completely complementary to said target portion if the nucleotide residue located at position 69 of SEQ ID No. 1 is thymine. Claim 28 is drawn to a kit further including an instructional material. Claim 33 is drawn to a microarray having at least one oligonucleotide probe that can anneal with a target portion of a mammal's genome, wherein the target portion includes the nucleotide residue located at position 69 of SEQ ID No. 1. Claim 34 is drawn to an microarray wherein at least one oligonucleotide probe consists essentially of nucleotide sequences selected from the group consisting of SEQ ID No. 6 and 7.

Despite knowledge in the art regarding how to mutate DNA molecules generally, the specification fails to provide guidance as to where and what type of changes in the claimed sequence will result in the retention of enzymatic activity, reduced enzymatic activity, or abolishment of enzymatic activity. The breadth of these claims is much larger than the scope enabled by the specification because the claims are drawn to mutations in the sequence, which are not bound by structure or function requirements of

FGF-3 because the structure and function requirements are not taught. The invention is in a class of invention, which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Guidance in the Specification

The specification teaches that the 5' untranslated region and promoter sequence upstream of the human FGF-3 gene was published as Genebank Accession Y12377 (p. 2, lines 14-16). The specification teaches there is a variant nucleotide at position 69 of SEQ ID No. 1 (a "C" or a "T" allele) present in the upstream untranslated region of the FGF-3 gene, extending form nucleotide residues 4945 to 5508 relative to the published sequence of FGF3 gene, extending from nucleotide residues 4945 to 5508 relative to the published sequence of FGF3 gene upstream flanking region (Genebank Accession Y123777) (p. 30 lines 30-35 and p. 4 lines 1-4). The specification teaches a SNP in the 5' proximal region of the FGF-3 promoter in which a cytosine is substituted for a thymine at position 69 in SEQ ID No. 1 (position –6693 relative to the ATG codon of the FGF-3 gene) (p. 4 lines 15-21). Accession Y12377 does have a "C" at position 69 relative to SEQ ID No. 1 of the instant application, but yet differs from SEQ ID No. 1 at position 70 relative to SEQ ID NO. 1 of the instant application. The wild-type sequence of FGF3 and the mutant sequence of FGF3 are unpredictable because the specification asserts that SEQ ID No. 1 is the same as the Genebank Accession Y12377 except for position 69 yet the two sequences differ at position 70 relative to the instant application's SEQ ID No. 1.

The specification does not teach any studies associating the specific SNP taught with the detection of cancer. The specification asserts that the kits are generally applicable to cancers of mammals of all sorts including primates, cattle, pigs, horses, sheep, cats and dogs (p. 21 lines 21-34). The specification does not teach the FGF-3 gene from any species other than human. The specification does not teach that SEQ ID No. 1 is observed in any other mammal besides human. The specification does not teach a representative number of variants within this broadly claimed genus of nucleic acids.

Working Examples

The specification teaches genomic DNA was obtained from 81 human subjects (39 Caucasians, 42 Chinese) and a SNP, C/T, was discovered at position 6693 bp upstream of the ATG start codon of FGF3 coding sequence (p. 22 lines 29-31). The specification teaches a TaqMan-based genotyping assay was performed to genotype DNA from 64 African American, 79 Caucasian, and 171 Chinese (p. 25 lines 1-5).

The specification does not teach any mammal other than human. The specification does not provide any correlation with the FGF-3 gene in humans compared to other mammals. It is unclear if a mutation in one species would have the same functional effect in another species. The specification only teaches the isolation of SEQ ID NO. 1 with a SNP of "C". The specification does not teach the variants, mutations, and homologs which are encompassed by the claim language of "complementary to" SEQ ID No. 1. It is unclear what sequence would be

"complementary" to SEQ ID No. 1. Claims drawn to a "target portion includes the nucleotide residue located at position 69 of SEQ ID No. 1." It is unclear what the defining nucleotides around position 69 have to be. It is unclear what nucleotides can flank SEQ ID No. 1 and still be considered FGF-3 gene.

The specification does not teach all critical nucleic acids for FGF-3 activity. The specification does not describe the structure of FGF-3 in a way that one skilled in the art could predict the functional effect of any type of mutation at any position. The specification provides no guidance as to what degree a sequence can be mutated and still be defined as a FGF-3 molecule. The specification does not provide a predictable correlation between the identity and location of generally any mutation and the predictability of its effect on enzyme activity. The effect of any mutation on the FGF3 molecule is unpredictable; therefore, there would be an undue amount of experimentation to determine if any sequence complementary to SEQ ID No. 1 in any mammalian species would have the same functional effect.

The unpredictability of the art and the state of the prior art

The art teaches that the relationship between FGF3 across species is not defined. The prior art teaches the nucleotide sequence of Human Int-2 gene (FGF3) presented in Genebank accession Y12377 (Y12377 March 2, 2000). The current art teaches the nucleotide sequence of Mouse int-2 gene presented in accession Y00848. An alignment of these two sequences presented no significant similarities nor did an alignment between the mouse accession and SEQ ID No. 1 of the instant application. It is unclear in this regard if SEQ ID No. is found in any other species and if it is if similar polymorphisms can be obtained between the species. Based on these teachings

probes designed to amplify a target of the FGF-3 gene from one species would not necessarily amplify the same region of another species.

The specification teaches that SEQ ID No. 1 is part of FGF-3 gene and point in the specification to Genebank Accession Y12377. It is unclear, though, based on the prior art what constitutes a FGF3 genes sequence. Accession Y12377, a FGF-3 sequence, differs from SEQ ID NO. 1 in one position. Accession Y12377 is identical to the instant specification SEQ ID NO. 1 for nucleotides 1-69 and 71-564 of the instant application (nucleotides 4945-5013 and 5015-5508 of Y12377). At position 69 (position 5013 of Y12377) there is a "C". The two sequences differ at position 70 (position 5014 of Y12377) in which the instant application SEQ ID No. 1 possesses a "G" whereas Y12377 possess a "T". Therefore it is unclear if SEQ ID No. 1 is a variant or a homolog of FGF3 or if SEQ ID No 1 is associated with another gene. It is unpredictable what the wildtype nucleotide is at position 69 relative to SEQ ID No. 1 of the instant application.

The specification and the prior art do not provide for predictable teaching of effect of any variation at position 69 of SEQ ID No 1, any flanking nucleotides around SEQ ID NO. 1, and any variation, mutation, or homolog which encompasses "complementary to SEQ ID No. 1". It is unpredictable how the variations will effect the function properties of the resulting nucleic acid. The specification and the prior art do not provide for predictable teaching of SEQ ID No. 1 in ANY mammalian species nor does the prior art give a predictable association of SEQ ID No. 1 and FGF3 gene.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters that would have to be studied. To practice the invention as broadly as it is claimed, the skilled artisan would be required to first

determine the effects of each of the possible variants on the function and structure of the protein.

The skilled artisan would need to perform undue experimentation to determine the correlation of SEQ ID No. 1 and any mammalian species because the specification does not teach any correlative sequence in any other mammalian species not does the prior art give any association between SEQ ID No. 1 and any mammalian species. The genus of sequences encompassed by "complementary to SEQ ID No. 1" is large and unpredictable, therefore the skilled artisan would have to do undue experimentation in order to determine all the sequences encompassed by the claims. Further the actual wildtype sequence of FGF3 is unpredictable and it is not clear based on the specification and the prior art the wildtype nucleotide at position 69.

To use the invention as presented would require a large amount of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

Thus the applicants have not provided sufficient guidance to enable a skilled artisan to make the claimed invention in a manner reasonably correlated with the scope of the claims because the scope of the claims include any modification of any nucleic acid molecule having unknown homology to SEQ ID NO. 1 and with unknown correlation of SEQ ID No. 1 with any mammalian species. Without sufficient guidance, determination of proteins having the desired biological function is unpredictable and the experimentation left to those skilled in the art is extensive. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the

large quantity of research required to define these unpredictable variables, and the lack of guidance provided in the specification balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 112-Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-5, 25-28, and 33-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to an isolated nucleic acid molecule comprising the sequence of SEQ ID No. 1. Claim 2 is drawn to an isolated nucleic acid molecule comprising a sequence complementary to the sequence of SEQ ID No. 1. Claims 3-4 are drawn to a vector wherein the reporter gene sequence encodes luciferase. Claim 5 is drawn to a host cell. Claim 25 is drawn to a kit comprising a first oligonucleotide probe which anneals specifically with a target portion of the mammal's genome, wherein said first probe comprises a first fluorescent label and a first fluorescence quencher attached to separate nucleotide residues thereof and said target portion includes the nucleotide residue located at position 69 of SEQ ID No. 1 and a pair of primers for amplifying a reference portion of the FGF-3 gene wherein said reference portion

includes the nucleotide residue located at position 69 of SEQ ID No. 1. Claim 26 is drawn to a kit including DNA polymerase having 5' to 3' exonuclease activity. Claim 27 is drawn to a kit further comprising a second oligonucleotide probe, wherein said first probe is completely complementary to said target portion if the nucleotide residue located at position 69 of SEQ ID No. 1 is cytosine and said second oligonucleotide probe is completely complementary to said target portion if the nucleotide residue located at position 69 of SEQ ID No. 1 is thymine. Claim 28 is drawn to a kit further including an instructional material. Claim 33 is drawn to a microarray having at least one oligonucleotide probe that can anneal with a target portion of a mammal's genome, wherein the target portion includes the nucleotide residue located at position 69 of SEQ ID No. 1. Claim 34 is drawn to an microarray wherein at least one oligonucleotide probe consists essentially of nucleotide sequences selected from the group consisting of SEQ ID No. 6 and 7.

The claims do not describe the number or identity of nucleotides flanking the recited nucleic acid fragment of SEQ ID No. 1. The claims encompass nucleic acids, which comprise any nucleic acid variant of any size, fragments of SEQ ID No. 1, and sequence, which are complementary to SEQ ID No. 1 for any number of nucleotides. The claims encompass variants, which include nucleotide substitutions, additions, deletions, translocations, and truncations. Claims encompass any number of sequences, which must include only the cytosine of position 69 of SEQ ID No. 1. The specification does not describe the sequences encompassed by "complementary to SEQ ID No. 1"

The claims also encompass a large genus of sequences from any mammal. The specification does not describe SEQ ID no. 1 in any mammalian species other than human.

The specification fails to describe the sequence variation of FGF3 with regard to what is considered a wildtype at position 69 of SEQ ID No. 1 and what is a mutant at position 69. Therefore the specification fails to provide reasonable clarity that the applicant had possession of a nuclide acid molecule wherein there was a nucleotide sequence variant.

The specification teaches that SEQ ID No. 1 is part of FGF-3 gene and point in the specification to Genebank Accession Y12377. It is unclear, though, based on the prior art what constitutes a FGF3 genes sequence. Accession Y12377, a FGF-3 sequence, differs from SEQ ID NO. 1 in one position. Accession Y12377 is identical to the instant specification SEQ ID NO. 1 for nucleotides 1-69 and 71-564 of the instant application (nucleotides 4945-5013 and 5015-5508 of Y12377). At position 69 (position 5013 of Y12377) there is a "C". The two sequences differ at position 70 (position 5014 of Y12377) in which the instant application SEQ ID No. 1 possesses a "G" whereas Y12377 possess a "T". Therefore the specification fails to describe at position 69 what are the wildtype nucleotide and the SNP mutation. The specification does not describe the percent identity of SEQ ID No. 1 to FGF3.

The specification asserts that the kits are generally applicable to cancers of mammals of all sorts including primates, cattle, pigs, horses, sheep, cats and dogs (p. 21 lines 21-34). The specification does not teach the FGF-3 gene from any species other than human. The specification does not teach that SEQ ID No. 1 is observed in any other mammal besides human.

The specification does not teach the percent structural identity needed for a sequence to be considered FGF3. The specification also does not indicate how much

variation a sequence may have; therefore, the claims with regard to the "target" sequences can be any number of variations, mutations, or homologs.

The specification describes Genebank Accession Y12377 as FGF3 and SEQ ID No. 1 as FGF3 with a SNP at position 69 of a "C" or a "T". Genebank accession Y12377 describes a "C" at position 69 relative to SEQ ID No. 1 of the instant application but differs at position 70 with regard to the instant claimed SEQ ID no. 1. The specification therefore does not adequately describe the wildtype FGF3 in a way to determine that "C" at position 69 is a SNP.

The genus of the claimed nucleic acids molecules encompasses substantial variability among the species of nucleic acids, but only a few mutations have been described. The genus of the claimed invention encompasses a large variable genus of mutants, variants, and homologs from any source. The genus of the claimed invention includes all mammalian species yet only describes examples used in humans.

The claimed genus of sequences encompasses mutants, variants, and homologs from any source, but the specification only teaches SEQ ID No. 1 from human. The specification fails to sufficiently describe the claimed invention in clear and exact terms so that a skilled artisan would recognize that the applicants were in possession of the claimed invention at the time of filing.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in

possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) In the instant case, the specification fails to teach the necessary common attributes or features of the genus of encompassed nucleic acids and mammalian species in view of the species disclosed. As such, one of skill in the art would not recognize that applicant was in possession of the genus of nucleic acids and polymorphisms encompassed by the broadly claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116).

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan

for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The sequences encompassed by the claims do not meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly diverse. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Genebank Accession Number (Y12377 March 2, 2000)

With regard to Claim 2, Accession Y12377 a FGF-3 sequence which differs from SEQ ID NO. 1 in one position. Accession Y12377 is identical to the instant specification SEQ ID NO. 1 for nucleotides 1-69 and 71-564 of the instant application (nucleotides 4945-5013 and 5015-5508 of Y12377). At position 69 (position 5013 of Y12377) there is a "C". The two sequences differ at position 70 (position 5014 of Y12377) in which the instant application SEQ ID No. 1 possesses a "G" whereas Y12377 possess a "T". Therefore Accession Y12377 encompasses the claim language of "complementary" to SEQ ID No. 1.

10. Claims 2 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5474796 December 12, 1995).

The claims are drawn to an isolated nucleic acid molecule that comprises at least 10 nucleotides. Brennan teaches an array which contains oligonucleotides with 10 nucleotides each (see Column 9, lines 49-50). Brennan teaches that the total array represents every possible permutation of the 10-mer oligonucleotide (see Column 9, lines 53-55). Therefore, Brennan teaches the possible 10-mer combination which is 100% complementary to the instant application's Seq ID No. 1.

Conclusion

11. No Claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Katherine Salmon 4/14/2006

Katherine Salmon
Examiner
Art Unit 1634

J. Goldberg

JEANINE A. GOLDBERG
PRIMARY EXAMINER
4/14/06